

**Department of Veterans Affairs
Quality Enhancement Research Initiative (QUERI)**

QUERI-HIV/Hepatitis

Strategic Plan
(Revised November 2008)

Steven Asch, MD, MPH
Allen L. Gifford, MD
Matthew B. Goetz, MD
S. Randal Henry, DrPH, MPH

VA Greater Los Angeles Healthcare System
11301 Wilshire Blvd.
Los Angeles, CA 90073
(310) 478-3711 x42556
(310) 268-4933 fax
Steven.Asch@va.gov
Allen.Gifford@va.gov
Matthew.Goetz@va.gov
Stephen.Henry@va.gov

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Executive Summary

The mission of QUERI HIV-Hepatitis is to improve the identification and care of veterans infected with the Human Immunodeficiency (HIV) and Hepatitis C (HCV) viruses.

To support our mission, we have developed three overarching goals: **1) Better Disease Identification**, **2) Better Chronic Disease Management**, and **3) Improve Access and Equity**. Goal #1 recognizes that the ability to confer the benefits from improvements in chronic illness care and treatment depends first and foremost on identifying infected people and getting them into care. Goal #2 acknowledges the need for comprehensive, coordinated care and treatment. Within this goal we have prioritized two broad themes: 1) *Medication Management* which is crucial to both HIV and HCV disease and 2) *Co-morbidity Management* because many HIV and/or HCV infected patients have multiple co-morbidities and disabilities across medical, psychiatric, economic and social realms that are strong determinants of outcome. Goal #3, new this year, reaches out to infected veterans at highest risk for impaired access, including African Americans, Latinos, the homeless, the impoverished, and those with mental health and substance use disorders. Additionally we will try to extend the benefits of specialist HIV and hepatitis care to underserved persons living in rural areas. Finally, we have set implementation science goals based on the Promoting Action on Research Implementation in Health Services (PARIHS) framework.

Highlights of Recent Accomplishments

Our QUERI has made enormous progress in the last few years. We are proud that our work has led to a three-fold increase in the likelihood that at-risk VISN 22 veterans will be tested for HIV; this project is now being implemented and evaluated in VISNs 3 and 16 in preparation for a national roll-out. In parallel to this we have contributed to the repeal of requirement for written consent for HIV testing in Congress this year, a development that should substantially ease future testing initiatives. Our expansion into HCV implementation research has been highly productive, with the number of funded, active projects increasing from one to six over the past year alone. In particular, we have focused on identifying disparities, improving disease management by assessing the quality of care and by testing new models of self-care.

We have also continued to build our internal and external network of collaborators and stakeholders, most especially in the Public Health Strategic Health Group (PHSHG). We now not only share Executive Committee (EC) members, but staff. We have joint projects with the

Substance Use Disorder (SUD) and Mental Health (MH) QUERIs. We will also continue to collaborate with VA clinicians, managers, and related organizations to develop, test and disseminate methods for achieving accessible, high quality HIV and Hepatitis Care.

A full description of our Active and Completed Projects is found in Table 3 of our Annual Reports (page 31) while a full listing of our Staff and Executive Committee Roster is found in Table 5 (page 38) of this report.

Key Features of Future Plans

During the coming years, we plan to extend our portfolio by engaging in projects that address strategies to further improve the availability of HIV testing. Specifically, we will work to develop methods of implementing routine offering of testing in high prevalence settings, in accordance with CDC guidelines and as a complement to our risk based testing projects. We will also continue to develop and test innovative methods for supporting medication adherence and controlling comorbid conditions, especially depression and substance abuse.

In HCV, we will continue to work on early QUERI stage quality assessment projects to better understand the patient and organizational determinants of effective treatment, liver biopsy, and other key processes. We will strive to develop and evaluate better methods for integrating mental health and substance use care into HCV treatment to improve treatment results. We will also work with our partners in PHSHG to disseminate the results of this and other interventions including HCV self management.

In both diseases, we will assess the extent to which medical care and quality improvement interventions improve or reduce equity. We will develop and test outreach programs to improve access and adherence to treatment for disadvantaged patients, especially homeless and rural veterans. In parallel with our work in all of these goals, we will continue to expand broader development of implementation science theory and models through insights from our projects.

We are quite proud of the expansion in our activities over the last year. We have broadened our expertise to include more implementation science theory, qualitative research and economics. Our principal investigators now span 5 VA Medical Centers and we now have a total of 18 active peer-reviewed and funded projects. Most importantly, we have demonstrated sustainable changes in practice as a result of several of our initiatives, especially in the area of HIV testing, and we expect more of the same in the years to come.

Part I. Center Mission, Goals and Scope

Mission

The mission of QUERI HIV-Hepatitis is to improve the identification and care of veterans infected with the Human Immunodeficiency (HIV) and Hepatitis C (HCV) viruses.

Goals/Scope

To support our mission we have developed three overarching goals, which we introduce here rather than in section 1.6 so as to better organize subsequent discussion. They are **(1) Better Disease Identification**, for which we have developed screening and case-finding project streams or initiatives; **(2) Better Chronic Disease Management**, for which we have developed provider behavior, adherence and co-morbidity management project initiatives; and **(3) Improve Access and Equity**, a new goal that reflects our efforts to address inequitable access and health disparities in the two diseases.

I.1 Clinical Focus and Scope

We have chosen to focus on both HIV and HCV care not only because of the clinical importance of these two chronic viral diseases, described below, but also because of the coincidence of risk factors and quality improvement stakeholders. The focus of our activities is based on an analysis of what would best serve the population of infected patients, and the place that QUERI occupies among the other stakeholders interested in improving HIV and HCV care. Here we describe the reasons for choosing the goals introduced in the last section and the limits of their scope.

Better disease identification for both these chronic infections is necessary to ensure timely access to appropriate treatment, reduced complications from untreated illness, better quality of life per healthcare dollar spent, enhanced length of life, and less disease transmission to others. Disease identification is a greater issue for HIV than HCV as the VA has been quite successful in disseminating and implementing HCV screening initiatives.^{1,2} Thus our focus in this area will be on developing and testing programs to improve the frequency and effectiveness with which HIV infected veterans are offered screening, both through risk-based and routine testing (as now recommended by the CDC³). We acknowledge the importance of activities to prevent primary infection by HIV and HCV, but at present leave these behavior-change activities to other VA entities (e.g. the National Center for Health Promotion and Disease Prevention [NCP], QUERI-SUD, and the VA Public Health Strategic Healthcare Group [PHSHG]).

Better chronic disease management emerges from the history of improving treatment for HIV and HCV. Over the past two decades in the USA, HIV infection has been transformed from a progressive and rapidly fatal disease, to a chronic illness that can be successfully managed with outpatient-based care throughout a long, active lifespan.⁴ Likewise, with modern treatments HCV infection is now manageable, and in many cases curable.⁵ But advances in treatments have been accompanied by new challenges for healthcare systems as a consequence of the need to provide adequate disease-specific chronic illness care to large numbers of infected ambulatory patients. Treatment is long and side effects are common, making it difficult for infected patients to maintain adequate adherence to complex medical regimens. Moreover, care for these patients must now be directed not only toward their primary diseases, but also at a variety of complicating comorbid conditions that in the modern era often dominate the illness experience of HIV and HCV patients.^{5,6} Thus our focus is on improving adherence to HIV drugs, better understanding the determinants of treatment in HCV, and integrating mental health and other co-morbid care into HIV and HCV care.

Improving access and equity emerges from the evidence that gaining access to medical care may make a difference for persons with HIV for a variety of outcomes, including mortality and quality of life.⁷⁻⁹ Further evidence suggests that this lack of access might lead to poorer outcomes for vulnerable populations. Access is defined as the actual use of HIV and HCV related services and everything that facilitates or impedes their use. As HIV and HCV occur more frequently among racial and ethnic minorities, persons with low-income, the unstably housed, substance users and otherwise disadvantaged populations, the importance of equitable access to healthcare services is highlighted.^{1,10,11} HIV and HCV are not just concentrated in the major population centers, thus while most prevalent cases are found in urban areas, the rate of increase in new cases is increasing at a disproportionately high in rural areas.¹²

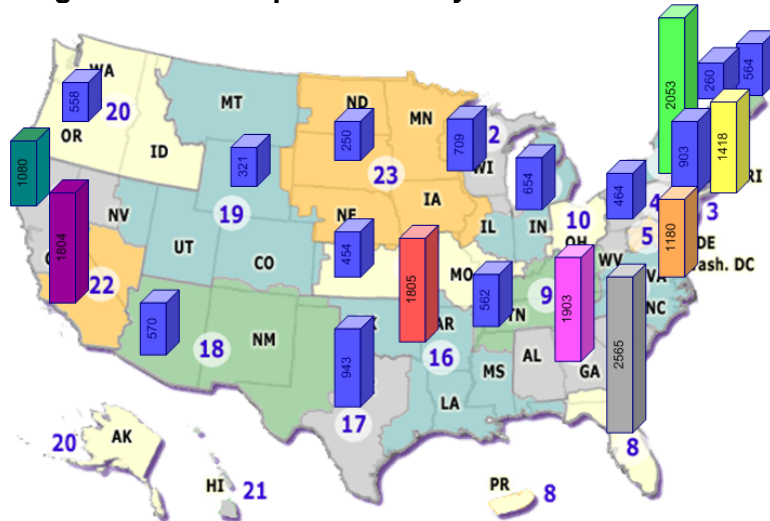
Another VA group (the Veterans Aging Cohort Study) covers age related disparities well, and the vast preponderance of VA HIV and HCV cases are men. Thus, while we acknowledge the importance of age- and gender-related disparities, we have chosen to limit our scope to the other, previously mentioned disadvantaged groups. Our access and equity agenda is new, and under development. For now, it focuses on adding analytic goals to existing projects to better understand how access and quality varies by these social determinants, especially in HCV where it is less studied, and how our existing interventions differentially affect these groups. We also plan to reach out to these populations in a number of targeted interventions.

I.2 Significance and Consequences

HIV

The burden of infection by HIV is high in the United States as a whole, and in the VA in particular. At the end of 2006 an estimated 1,056,000 to 1,156,400 persons in the United States

Figure 1. VA HIV prevalence by VISN FY 03



were living with HIV/AIDS.¹³ In 2006 alone, 35,314 new cases of HIV/AIDS in adults, adolescents, and children were diagnosed in the 33 states with long-term, confidential name-based HIV reporting.¹³ Up to 25% of infected patients are unaware of their infection, and these patients are the fuel that feeds the epidemic's fire. The VA provided care for more than 25,000 HIV infected

veterans in 2007 and is *the largest single provider of HIV/AIDS care in the United States*.¹⁴ Electronic registry data show a well-distributed prevalence of HIV/AIDS patients in VA facilities throughout the country although increased concentrations are seen in the southwestern, southern, and eastern seaboard states (see Figure 1). Four in ten HIV-infected patients in the VA are under 50 years of age; and another four in ten are between the ages of 50 and 60.¹⁴ African-American and Latinos more likely to be infected with HIV. For example, even though African Americans account for ~13% of the US population, they account for about half (49%) of the people who contract HIV/AIDS.¹⁰

The transformation of HIV to a chronic disease means that treating the illness can extend not only length of life, but quality of life.^{2,4} However, quality of life remains a serious problem for HIV infected patients. Physical functioning and emotional well-being in symptomatic HIV patients are well below normal, and worse than for most other chronic diseases.^{15,16} As suggested above, this is at least partially due to comorbid disease. The proportion of deaths from HIV/AIDS or opportunistic infections¹⁷ has declined precipitously in the last 15 years from 43% to 13% , while death among infected individuals from other diseases has increased. Surveys have found multiple co-morbidities among HIV infected patients, such as depression (49%), smoking (44%), hypertension (45%), hepatitis (41%), and hypercholesterolemia (37%).¹⁴

These support the expansion of our research agenda to associated co-morbid conditions (e.g. HCV, mental health and substance use disorders) in HIV-infected patients.

Managing HIV/AIDS is costly. Although almost 70% of HIV-infected patients in the VA Healthcare system are on anti-retroviral therapy, a growing fraction of the cost of care is due to the comorbidities commonly seen in these patients. The overall average annual cost of care for HIV/AIDS in the VA in 2000 was \$13,899 per patient,¹⁸ which falls about mid-range for cost of serious chronic conditions seen generally in the VA. Outpatient pharmacy costs alone, however, showed HIV/AIDS leading the group by a substantial margin.¹⁹ In the constant quest for more effective therapies, expensive drugs are frequently entering the market, driving the cost of drug treatment ever higher. Thus the costs of care have continued to increase as the HIV patient population ages and the costs of antiretroviral therapy continue to rise.²⁰ Although improved drug regimens keep inpatient stays down and longevity up, financial savings may not be realized because of the expense of these new drugs.

HCV

HCV infection is an order of magnitude more prevalent in the VA than is HIV/AIDS.^{2,14} Like HIV/AIDS, HCV is transmissible in blood and body fluids, and patients who have injected drugs or had numerous sex partners are at highest risk. These patients are heavily overrepresented in the VA.^{1,21} In response, the VA has been a world leader in identifying HCV infection, with rates of HCV screening exceeding 90%. Currently there are over 208,000 known HCV-infected veterans in VA care, making it the largest provider of HCV services in the country.² Although 15 – 30% of persons infected by HCV have spontaneous resolution of infection (i.e., clearance of viremia or viral RNA) within the first year of being infected, many more remain chronically infected long-term. HCV infection is more indolent than HIV; the consequences of long term infection, e.g., cirrhosis, liver failure, and hepatocellular carcinoma can take years to develop.⁵

Depending on viral factors (e.g., the viral genotype and the level of viremia) and host factors (e.g., ethnicity, obesity and adherence to therapy), HCV can be cured. However, the required 6 – 12 month course of treatment with interferon injections and oral ribavirin therapy is often poorly tolerated, especially in persons with underlying histories of substance abuse or mental illness. Because interferon exacerbates underlying depression, mental health diagnoses can strongly contraindicate or complicate interferon administration.⁵ For that reason, chronic HCV disease management is increasingly team-based and attempts to integrate a variety of mental and physical health services to address complex interrelated health problems in order to maximize adherence and outcomes.²² The average annual cost of HCV care in the VA in 1999

(most recent data available) has been estimated at \$12,898 per patient.¹⁹ The costs of care are likely to have subsequently increased dramatically with the increasing use of combination anti-viral therapy with Pegylated-interferon and ribavirin, and increasing rates of uncompensated cirrhosis, hepatocellular carcinoma and liver transplantation.²

I.3 Treatment/Management Evidence Base

Evidence for effectiveness of disease identification

QUERI-HIV/Hepatitis stresses the importance of early HIV/AIDS identification. Asymptomatic individuals who are HIV-positive but have not been tested do not know their serostatus and thus cannot access appropriate care until the onset of immunological failure and the emergence of symptoms. Based on older cost-effectiveness models, the CDC previously recommended screening all patients in populations with a known frequency of HIV of more than 1%.²³ This includes people with a history of intravenous drug abuse, men who have had sex with men, and people who have had unprotected sex with more than two partners in the last five years, or risky primary sexual partners;^{24,25} such groups are overly represented in the VA population.²⁶ Subsequently, work by QUERI-HIV/Hepatitis Executive Committee member Douglas Owens and others has shown that adoption of routine, non-risk based HIV testing, which results in earlier diagnosis of HIV infection than occurs with risk- or symptom-based testing, results in improved clinical outcomes and is cost-effective even in populations with a seroprevalence rate of 0.05%.^{27,28} This has led the CDC to recommend routine HIV testing in populations where the seroprevalence of HIV infection is not known to be less than 0.1%.³ The overall HIV prevalence in the VA patient population far exceeds this 0.1% threshold.²⁹ Routine blood based testing (for which test results are not available for at least one and often 3 -5 days) is of benefit in many circumstances. However, rapid oral testing and streamlined counseling may lead to improved screening and increased access to care, especially for patients with poor follow-up because it reduces test result wait times from several days to 20 minutes. Patient identification and intake can be accomplished in one visit, circumventing the problem of visit-to-visit patient attrition.³⁰

Early disease identification is also of benefit to persons infected by HCV. Administration of specific antiviral treatment delays progression to cirrhosis and hepatocellular carcinoma and is more curative and better tolerated in persons in the earlier stages of disease. Furthermore, early case recognition allows for patients to be counseled about alcohol and substance use and, as appropriate referred to treatment programs; these are measures of great importance given

that such behaviors greatly accelerate the course of liver disease in HCV-infected individuals.^{5,31} Fortunately, in recognition of the increased rates of HCV infection in the VA,³² the VA has already developed a highly effective program to identify patients at risk for HCV-infection and to offer such persons diagnostic testing.^{1,33}

Evidence for effectiveness of chronic disease management

Effective treatments for HIV/AIDS and HCV are generally well-defined and strongly evidence-based. In HIV, robust guidelines specify appropriate antiretroviral therapy, prophylaxis for opportunistic infections, and tests for monitoring disease progression.^{5,5,34-38} Furthermore, as HIV is transformed into a manageable chronic condition and as the HIV-infected patient population ages³⁹, evidence has emerged and guidelines have been developed regarding the management of the increasingly prevalent co-morbidities, i.e., diabetes, depression, hypertension, cardiovascular, renal and hepatic disease.^{14,34,36,37} This evidence base helps form the basis for the QUERI-HIV/Hepatitis goals (see Section 1.6).

The challenges of HCV therapy are somewhat different, but equally demanding of patients. Untreated, HCV infection progresses very slowly, and is asymptomatic often until liver damage is quite advanced.⁵ Depending on when infection occurs, some patients may never experience problems with HCV before succumbing to other unrelated illnesses, possibly at advanced age. However, HCV is most the common cause of liver failure in the United States, leading many infected patients to suffer from serious disability as well as death from end-stage liver disease. The beneficial effects of specific anti-viral treatment and interventions to reduce alcohol and substance use are well-demonstrated.^{5,40} However, many patients, especially in the VA are considered to be poor candidates for receipt of potentially curative treatment because of underlying mental illness or substance use.^{11,41} Because of the potential reversibility of these conditions, extensive attention has been paid to determining the best ways of managing these co-morbidities and thereby allow more patients to become candidates for anti-viral treatment of HCV. Evidence from trials of integrated care is available on the integration of substance use and psychiatric treatment with primary medical care. The strongest trial compared usual outpatient care with alcohol interventions integrated into long-term primary care for medically ill alcoholics at a VA facility.⁴² Patients in the integrated model had significantly better drinking outcomes and a trend towards reduced mortality over two following years. The incremental cost of the model was an estimated \$1100/patient /year. Another study among US veterans with alcoholic liver disease found that repeated monthly contacts with nurses over the course of the study resulted in substantial decreases in drinking among all study participants.⁴³ These

studies suggest that for persons with alcohol dependence, non-intensive medically focused attention to drinking can result in substantial improvement in outcomes.

Evidence for addressing access and equity

There is substantial evidence that gaining timely access to medical care improves a variety of health outcomes, including mortality and quality of life, for HIV-infected patients.^{4,27,44} For persons with known HIV infection having subsequent timely, consistent and equitable access to care has been associated with improved clinical outcomes.^{7,8} Because of the chronic, incurable nature of HIV infection, optimal care requires that patients maintain consistent, frequent contact with their providers.³⁴ Patients who do not maintain regular clinic attendance are less likely to ever receive antiretroviral therapy and more likely to miss medications once prescribed. As a consequence such persons have higher levels of plasma HIV and higher rates of drug-resistance.^{8,45,46}

Assuring equity also requires that attention be paid to promoting consistent adherence to medication taking behaviors as access to care alone is not sufficient to ensure optimal outcomes.⁴² Partial adherence and frequent switching of drugs in response to side-effects and adherence problems can in turn lead to drug-resistant HIV isolates which may not respond even to well-planned therapies.³⁸ Sub-optimal adherence to medical recommendations (e.g. poor follow-up appointment keeping) in general and poor adherence to medication also leads to sub-optimal use of drug therapy in VA HIV patients.⁴⁷ Similar findings have been found among vulnerable HCV-infected patients.^{48,49}

I.4 Current Practices and Quality/Outcome Gaps

The second step in the QUERI model for approaching the implementation of quality improvement interventions is assessing variations in the quality of care as defined by guidelines, and characterizing determinants of variations. The work we and others have done that documents such variation is here categorized by our three clinical goals.

Gaps in disease identification.

Approximately a quarter of HIV-infected people in the USA do not know that they are infected.⁵⁰ Furthermore, QUERI-HIV/Hepatitis research suggests that about two-thirds of VA patients at clear risk for HIV infection are not tested.^{21,51} The consequences of the failure of current strategies to identify HIV disease early have been demonstrated; fully half of all VA patients with newly diagnosed HIV infection have 200 CD4⁺ cells/ μ L or fewer; a degree of

immunodeficiency which presages the imminent development of severe infection and neoplastic complications of HIV.²⁸ These gaps in diagnosis exist despite evidence that HIV screening programs for all veterans would be cost-effective.²⁷ Of note, although the CDC recommendation for routine HIV testing unless the prevalence of infection is less than 0.1% applies only to 13 – 64 year olds,³ work done in the VA by QUERI collaborators demonstrates that HIV testing is cost-effective in sexually active persons up to the age of 75.⁵² The relevance of these screening recommendations to the VA is underscored by the results of a blinded serological survey done by a QUERI-HIV/Hepatitis collaborator wherein the prevalence of undiagnosed HIV infection ranged from 0.1% – 2.8% among outpatients at six VA facilities.²⁹

Access is affected not only by failing to offer patients HIV testing, but by case finding gaps as well. Results from a project evaluating the accuracy and completeness of the VA Immunodeficiency Case Registry (ICR) revealed that nearly 2,500 patients in the VA's electronic medical record with probable HIV disease in FY1999 were not included in the VA HIV registry; only 20% of these were entered in subsequent years. A review of this group's utilization patterns is consistent with inferior access to care. Such patients were less likely to receive antiretroviral therapy or to visit an HIV clinic, and more likely to visit urgent care than those included on the ICR.⁵³

As a consequence of the extensive attention already paid to identifying patients with HCV, disease identification is a smaller issue among HCV infected persons than it is among the HIV infected population.^{1,33} As a result, our efforts focus less on that goal than they do on improving the quality of chronic illness disease management for HCV-infected patients and for improving access to care and equity for disadvantaged patients, rural patients, and racial and ethnic minorities with HCV infection.

Gaps in chronic illness management

For those who already have access to specialized HIV care, highly active antiretroviral therapy (HAART) has proven effective¹⁷; guidelines for HAART use are clear, and HAART uptake within and without the VA has been rapid and effective.^{54,55} However, compliance with other quality indicators is less complete.¹⁴ In the early 2000's QUERI-HIV/Hepatitis developed 10 HIV quality indicators based on existing guidelines. Using these indicators to evaluate VA performance in our first implementation project, 'Improving HIV Care Quality', we found care quality to be similar to a national non-VA sample, though both VA and non-VA care had room to improve; this formed the basis of a subsequent successful implementation project. Still gaps

remain. A survey of VA HIV patients found that physical and mental functioning were well below normal for age and sex.

One possible cause for this outcome gap is a gap in adherence to therapy. Research Co-Coordinator (RC) Allen Gifford's data from VA patients using HAART indicated that 28% were adherent less than 80% of the time.⁴² In the QUERI-HIV/Hepatitis patient survey, 16% said that they missed doses of their antiretroviral therapy at least once a week. Objective, electronically-monitored antiretroviral adherence data from the QUERI-HIV/Hepatitis **ACE** project showed worse adherence – as low as 60-65%.⁵⁶

Another likely cause for poor outcomes is suboptimal treatment of comorbid conditions. Depression, in particular, is a common co-morbid condition that is widely under diagnosed in HIV-infected patients^{6,14,57}. The Veterans Aging Cohort Study, an ongoing cohort study of veterans with and without HIV infection,⁵⁸ demonstrated that providers are often unaware of important comorbid conditions including hazardous alcohol consumption,^{59,60} and depressive symptoms.⁶¹ A lack of screening applies not only to alcohol use or mental health issues. For example, despite the high risk for dyslipidemia faced by patients with HIV who take certain antiretroviral drugs, our own work has revealed that in the VA only 59% of these patients receive appropriate lipid monitoring tests within six months of initiating treatment⁶². Despite the development and promulgation of guidelines^{36,37}, screening rates for dyslipidemia remained low as among the 16,833 veteran patients receiving antiretroviral therapy in FY 2007, only 63% had any tests to monitor for the presence of dyslipidemia.¹⁴ Data from provider focus groups confirm these challenges in managing co-morbidities in HIV-infected patients, indicating that the biggest challenges in managing HIV-infected patients relate to issues of medication adherence and management of concurrent conditions, such as HCV co-infection and mental illnesses.⁶³

Our ongoing HCV studies identified similar gaps in care. For example, Kanwal et al. found that antiviral treatment rates are low among patients who may be eligible for treatment and that these rates vary greatly.⁴⁸ This analysis revealed that fewer than 16% of eligible patients received antiviral treatment and that treatment rates varied across several patient characteristics and providers' experience (for example, patients seen by less experienced providers are less likely to receive treatment than those seen by more experienced providers), and across treatment facilities (for example, treatment rates varied from 6% to 28%). Even in patients in whom treatment is highly effective (that is, those with HCV genotype 2 or 3) and in patients more likely to be interested in pursuing treatment (that is, those who underwent a liver biopsy) treatment rates were lower than 50% and varied significantly across providers' experience and treatment facilities.

Gaps in access and equity

In recognition of the substantial barriers faced by disadvantaged populations and otherwise vulnerable patient groups, we have adopted improving access and equity as a strategic goal.

Many studies have found that patients who are women, older, members of racial and ethnic minorities, poorer, less educated, or uninsured are less likely to receive needed care, largely as a result of lack of access to care (determined by whether an encounter with a health care provider occurs), rather than a deficiency in the quality of care (determined by whether the encounter is necessary and provides the recommended service).⁶⁴

Despite the reduction of barriers typically faced by disadvantaged populations in the non-VA setting, Saha et al found that racial disparities in the VA exist across a wide range of clinical areas and service types. Disparities appear most prevalent for medication adherence, surgery and processes that are impacted by the quality and quantity organization-patient interaction and patient-provider communication.⁶⁵ The evidence for gaps in access is strong for HIV^{7-9,66} and developing for HCV^{48,49}.

Because disadvantaged populations including, homeless patients, rural patients, racial and ethnic minorities, and those with substance use disorders have greater need, there is an argument that they should receive more not less care. Yet we often find the opposite. For example, African-Americans with HIV infection are less likely to receive timely antiretroviral therapy.^{7,9,67} Among HCV-infected persons, Rousseau et al⁴⁹ found that African Americans were less than half as likely as whites to receive antiviral HCV treatment and were significantly less likely to have complete laboratory evaluation and viral genotype testing. This was confirmed by Kanwal, who found that HCV-infected African American patients were less likely to receive antiviral treatment⁴⁸.

I.5 Significant Influences on Current Clinical Practices and Outcomes

As noted above, HIV and HCV should now be viewed as treatable chronic conditions. As such, they share a number of characteristics with other chronic conditions that shape current clinical practice and outcomes. First, they are often incurable; hence goals of treatment are not cure but containment, slowed progression, and symptom management. They also follow an often unsteady and episodic disease trajectory; require a great deal of adherence to treatment regimens and self-care; can carry social stigma; and have significant impact on a patient's psychosocial circumstances (e.g., relationships, careers).⁶⁸ This has implications for how we

view the institutional and other influences on improved outcomes, and has greatly guided our project selection and implementation strategy.

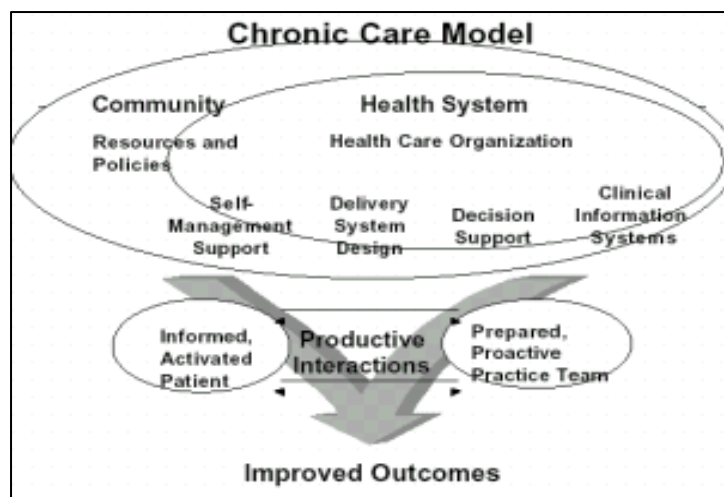


Figure 2: Chronic Care Model (Wagner et al.)

The problem is that the US health care system (and the VA) was originally designed for delivery of acute care in isolated clinical encounters, not chronic disease management, which must deal with the features described above. The Chronic Care Model (CCM)⁶⁹ (see Figure 2) was developed in response to this fact. It emphasizes the importance, in managing chronic

illness, of a comprehensive, coordinated, systems approach to care that promotes productive interactions between active, informed patients and prepared, proactive, professional health care teams. It accounts for the enduring nature of chronic care and recognizes that “effective chronic illness management requires comprehensive system changes that entail more than simply adding new features to an unchanged system focused on acute care”.⁷⁰ Accordingly, the elements of the CCM that are brought together in interactions between patients and practice teams are: the community that the health care organization is part of; the health care organization itself; and the organization’s self-management support system, care delivery system, decision support system and clinical information system.

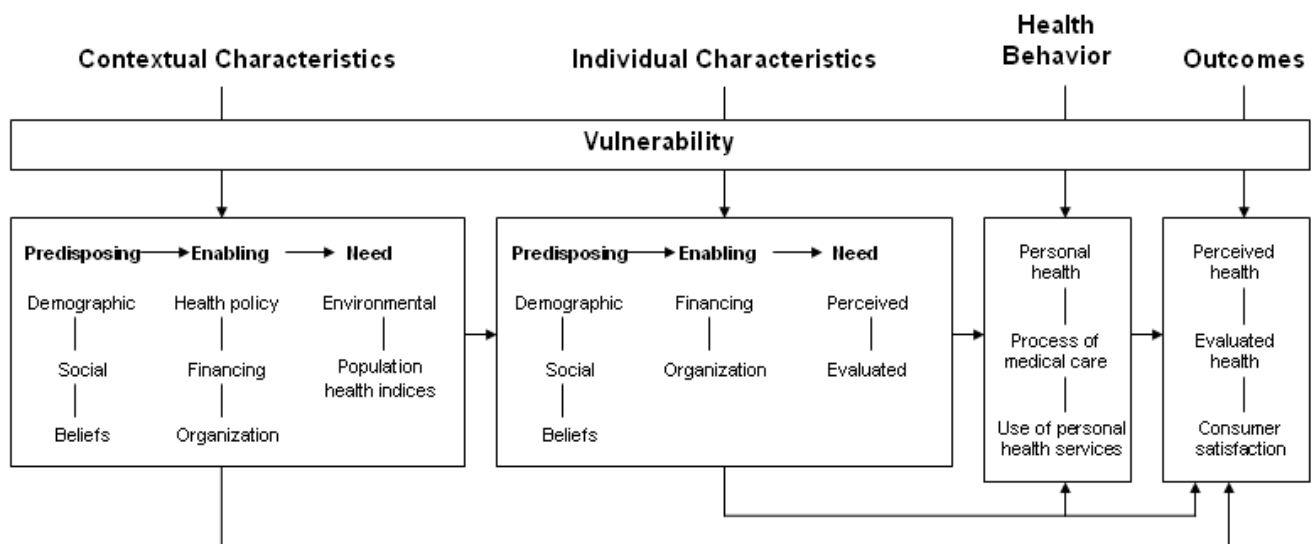
By identifying elements that are crucial to high-quality chronic disease management, the CCM has helped us to prioritize project proposals. This focus has, for example, led us to include projects promoting (a) system-supported self-management for better adherence (e.g., through use of a computer-assisted adherence tool); (b) delivery system redesign (e.g., promoting earlier treatment by allowing nurses to provide rapid tests for HIV); (c) decision support tool expansion (e.g., HIV testing clinical reminder); and (d) clinical information system enhancements, to facilitate coordination of care (e.g., through electronic clinical reminders, and systematic entry into the HIV ICR registry).

Although community support for care, which is represented in the CCM, is beyond the QUERI program’s mission, the CCM has led us to reconsider ways to enhance the community’s role in VA HIV care. To this end, we have now joined with PSHSG to work with and be guided

by their Veterans National HIV Community Advisory Board (CAB). A member of the National HIV CAB (Donald MacIver) is a voting EC member, and will assist with liaison.

In addition, attention to organization dynamics is highly effective in improving the delivery of many clinical services.⁷¹ Recognition of the importance of organizational factors has led the VA to invest in detailed nationwide analyses regarding the organization and process of care at VA facilities, including their relevance to HIV care.⁷²⁻⁷⁴ Organizational issues are particularly relevant to HIV testing, where the cumbersome nature of current HIV counseling procedures is a contributor to low HIV testing rates.⁷⁵ Evidence from urgent care clinics, emergency departments, and STD clinics show increased HIV testing rates and patient receipt of test results after implementation of structural changes such as reducing phlebotomy wait time, improved staff training in pre- and post-testing screening, introduction of streamlined counseling, and substitution of telephonic post-test counseling in place of a required return visit for face-to-face notification of test results.⁷⁶⁻⁷⁸ Lack of return for test results is also a particularly significant contributor to the HIV epidemic. In a recent study, almost 1/3 who tested HIV-positive did not return for their results.⁷⁹ This unawareness of their status on the part of so many infected individuals has staggering implications for the spread of the HIV epidemic. CDC data suggest that those unaware of their HIV-positive status are 3.5 times more likely to infect others than those who are aware of their HIV status.⁸⁰

Diagram 1. The Behavioral Model for Vulnerable Populations



For our third content goal of improving access and equity, we utilize the Behavioral Model of Health Services Use for Vulnerable Population (BMVP) to categorize influences on

realized access. Access is defined as the actual use of HIV and HCV related healthcare services and everything that facilitates or impedes their use. The BMVP suggests that traditionally vulnerable groups such as African Americans, Latinos, and injection drug users (IDUs) are less likely to receive appropriate HIV treatment and more likely to experience delays in receiving appropriate HIV treatment. Evidence suggests that poor access and inequitable distribution of care and the benefits derived from such might lead to poorer outcomes for vulnerable population groups. The BMVP suggests that the use of HIV or HCV care services and the benefit received from health care utilization can be explained by a series of variables representing (1) individual and organizational predisposition to provide care to vulnerable groups; (2) organizational factors that enable or impede the use of services by disadvantaged populations; and, (3) the extent of their need for care both as they perceive it and as medical care providers evaluate it.⁷ These variables provide the theoretical foundation for our efforts to reduce health disparities among vulnerable populations and otherwise disadvantaged groups. Please refer to the Diagram (Diagram 1. The Behavioral Model for Vulnerable Populations).

I.6 QUERI Center Goals

Our three overarching goals (**Better disease identification**, **Better chronic disease management**, and **Improve access and equity**) have been introduced and explained above. Here we provide the theoretical background that supports and guides the development of our implementation efforts. Additionally, we provide some examples (outlined in Figure 5 on page 33) of implementation science goals and action steps we have taken in the last year, or are now pursuing to address the goals. The figure is not intended to be exhaustive, but to show some examples of how QUERI-HIV/Hepatitis is working to use applicable theory, applied to our portfolio of projects, to elucidate key aspects of implementation science.

The Promoting Action on Research Implementation in Health Services (PARIHS) model serves as the theoretical framework for our implementation science goals. PARIHS posits that successful research implementation is a function of (1) *the nature and types of evidence* (meld and balance of research, clinical experience, patient experience and routine information), (2) *the qualities of context* (organizational features, culture, innovation environment), and (3) *the way the process is facilitated* (human support, guidance, learning, “readiness”). The framework considers these elements to have a dynamic, simultaneous relationship. PARIHS proposes that for implementation of evidence to be successful, there needs to be clarity about the nature of the evidence being used, the quality of context, and the type of facilitation needed to ensure a successful change process. The PARIHS framework, which emphasizes the importance of

context, evidence, and facilitation, was used as a model for the development of our implementation science goals. PARIHS examines organizational support for evidence (e.g. best practices or clinical guidelines), contextual factors related to adoption and implementation (e.g. organizational capacity), and the actual facilitation (e.g. fidelity to intervention protocol) of evidence-based interventions. As we expand our implementation science portfolio, we will rely upon the PARIHS model as it has become an increasingly important tool for implementation scientists.⁸¹

Further guidance for our implementation strategy is provided by Rogers, whose seminal work on diffusion promotes the use of opinion leaders or champions to facilitate change or innovation adoption, and highlights the importance of individuals' social networks, organizational leadership, and organizational structure⁸², and by the PRECEDE-PROCEED⁸³ models. Additionally, CCM which examines current practice standards, also provides a useful framework for ensuring success during implementation. These theoretical approaches reinforce the importance of evidentiary support, emphasize the complexity of health care systems, highlight the importance of organization-level/patient-level interface (e.g. integration of care or the lack thereof), provider/patient preparation and activation, and stress the critical nature of facilitation suggested as a key component as a key element implementation.

I.7 Plans for Achieving QUERI Center Goals

QUERI-HIV/Hepatitis has three broad project management goals, which are shown graphically in the implementation pipeline diagram. The following paragraphs describe our future plans, and are likely best understood in reference to the Pipeline Diagram (see Figure 3 on page 29). For a more detailed description of current work, please refer to the 2008 Annual Report. In addition, we discuss here our plans to maintain, expand and deepen the wide network of collaborators that are so crucial to accomplishing our goals (see Figure 4 on page 30).

Goal #1: Better disease identification

Disease identification is a major quality gap in VA management of HIV disease. Our efforts to promote more HIV testing are two-pronged. First, we will build up organizational capacity to provide testing based on behavioral and other risk factors. We are proud that we have already demonstrated success in a VISN-wide implementation (**VISN-QI**) of a project that has put into place many of the elements of the chronic care model. Strategies include a computerized clinical reminder, provider activation and social marketing, and removal of

systemic barriers. Our group's premier planned implementation project, **MultiVISN QI**, just now underway, building on the single-VISN success. **MultiVISN QI** aims to improve testing of at-risk populations and test roll-out strategies in two more VISNs (VISN 3 and VISN 16). The goals of this extension of the **VISN-QI** project are to assess the barriers and facilitators to generalizability of this intervention across facilities with differing institutional cultures and to assess the efficiency and effectiveness of differing methods of implementing the intervention. We expect that the results of this project will provide the necessary foundation for a national roll-out of this program in the VA.

Second, we will test complementary strategies to routinize HIV testing among all adult patients (rather than just those with known risk behaviors), consistent with recent expert guidelines. In order to vastly upscale HIV counseling and testing, procedures will need to be greatly streamlined. We are proud to have recently completed the **Rapid Test** project, which showed that streamlined HIV counseling, routine nurse offers, and rapid HIV testing led to quite high testing rates without decrements in knowledge. Our planned extension of this project **Rapid Test II** tests the role of local champions in a multi-center national roll-out of this strategy (**Rapid Test Rollout**). Other smaller projects currently or will evaluate methods of further streamlining HIV test counseling (**HIV Kiosk**) and making communication about HIV tests more effective (**ARTCH**).

Low rates of HCV disease identification through clinical testing is a significant problem within the U.S. healthcare system at large, but due to system-wide efforts this is not currently a major quality gap within the VA. Therefore, our HCV disease identification efforts focus on disseminating VA lessons-learned to non-VA healthcare systems. The new **HepCAT** project is underway and will be completed in the upcoming year, and is implementing and evaluating reminders, social marketing, and activation methods for boosting HCV testing in a series of community clinics in the Bronx, NY.

Goal #2 Better Chronic Disease Management

Our major project in chronic HIV disease management addresses the key issue of HIV medication adherence. Multi-drug HIV regimens are highly efficacious, but must be taken consistently by patients, and often aren't. **MedCHEC** is multimodal program to improve adherence support in HIV clinics by using tablet touch-screen computers to assess adherence, and behavioral care managers to *support and counsel* patients to improve adherence, when needed. **MedCHEC** is now beginning a multi-site trial to assess effectiveness. If successful, we will plan a subsequent project to roll it out to more sites. A second major HIV disease

management initiative is the successful **HITIDES** project, nearing completion at the Houston, Arkansas, and Atlanta VAs. **HITIDES** uses case management to integrate care for depression within HIV clinics.

As we have rapidly expanded our Hepatitis agenda over the past year, our new HCV projects have nearly all focused on understanding HCV disease management, and improving the integration of HCV and comorbidity care. Drs. Samuel Ho, a VA San Diego-based gastroenterologist and former head of the Minneapolis VA Hepatitis C Resource Center, has teamed with Erik Groessl, a VA San Diego-based psychologist, and received HSRD IIR funding to test effectiveness of a protocol-based integrated care model merging psychological and substance abuse support within HCV specialty clinics to improve HCV treatment outcomes (**HCV Care Model**). If patient evaluation and treatment rates can be increased with this approach, then further VA dissemination/implementation will be planned. The appropriate approach should also integrate findings from the successful **HCV Self Management** project.

Improving antiviral treatment in HCV is challenging because treatment alternatives are evolving rapidly. Thus some major HCV disease management projects are at earlier QUERI stages, identifying and explaining care gaps by examining determinants of treatment offer and adherence with quantitative (**HCV Quality**) and qualitative (**Completing HCV Treatment**) methods.

Goal #3: Improve Access and Equity

This third QUERI-HIV/Hepatitis goal is new; our strategic plans are still very much under development, interacting with the other two broad goals. Efforts have been underway to better deliver care to those with access and equity vulnerabilities, but as these have grown, we think that these will in future best be managed as a new, separate area. We will continue key projects to identify disease in targeted disadvantaged care settings: Examples here include **Homeless Rapid Test**, **Rapid Test in ER**, and **Rapid Test in SUD**, and **HepCAT**. The **Appointment-keeping** initiative is designed to improve access to high quality disease management among the disadvantaged, who need help keeping appointments. In the upcoming year, we will develop rural **Telehealth** outreach to bring the benefits of specialist HIV and HCV care to rural veterans.

As is fitting with a new strategic goal, in the upcoming year we will emphasize identifying new advice and collaborations in access and equity. Dr. Henry (IRC) presented a workshop at the 2008 QUERI National Meeting titled “Addressing Health Disparities: Treatment Challenges and Collaborative Opportunities to Improve Care for Veterans with HIV/AIDS or Hepatitis” to stimulate collaborative research activities, especially among other QUERI IRCs. We are adding

collaborations with, and links to the Center for Health Equity Research and Promotion (CHERP), and the VA East Coast Rural Health Resource Center (White River Junction, VT) as well.

Expanding and deepening collaborative networks

The connections described above are just one aspect of our ongoing efforts to expand and deepen a collaborative network that can allow all QUERI-HIV/Hepatitis quality improvement projects and new knowledge thrive. Making these relationships work requires continual efforts to communicate well, to meet partners needs, and to recognize/share/give credit. As in the past, the Public Health Strategic Healthcare Group (PHSHG) is responsible for shaping and driving VHA clinical HIV and hepatitis policy and is our lead operations partner. PHSHG's resources, influence, and acumen partner QUERI-HIV/Hepatitis with a centralized, influential team for dissemination and sustainability. Within the PHSHG umbrella are a number of linked, vitally important centers with distinct, complementary roles. These organizations are each individually centers of crucial expertise. One example is the VA Palo Alto-based Center for Quality Management (CQM), manages national HCV and HIV registries, facility-level HCV and HIV informatics tools, and rolls out many safety and QI initiatives. The four Hepatitis C Resource Centers (HCRC) are another resource. Under the leadership of David Ross (Director, National Clinical Public Health), HCRCs provide multidisciplinary clinical expertise and roll out Hepatitis tools and education/QI products of all types. All these groups are central to our Executive Committee leadership (see Figure 4 on page 30).

Working relationships with PHSHG, CQM, HCRC and other partners allow us to channel our findings directly to VA HIV and HCV treatment providers. The relationships are structured around (1) bimonthly general update and strategy meetings and conference calls; and (2) joint 50% QUERI-HIV/Hepatitis and 50% PHSHG relationship support for Jane Burgess (former PHSHG Deputy Chief Consultant) - located in Los Angeles and charged with acting as national program liaison and conduit; (3) engagement of numerous PHSHG partners as named co-investigators or collaborators on QUERI-HIV/Hepatitis funded projects.

Other active outreach to VA programs and organizational entities includes representation on the national VA HIV Technical Advisory Group, the VA Infectious Diseases Field Advisory Committee, the VA national Medication Advisory Panel and the VA Society for the Practice of Infectious Disease (Matt Goetz, Clinical Coordinator, is past-president), as well as on local and VISN-level committees such as the VISN22 Quality & Performance Improvement Council. These allow our efforts to be directly informed about important performance and quality improvement, implementation, and HIV-specific issues.

Outreach beyond the VA is also important. As one of several examples, our EC member and San Francisco VAMC Chief of Medicine Paul Volberding is also co-editor-in-chief of the *Journal of Acquired Immune Deficiency Syndromes*, founder and chair of the International AIDS Society-USA, and co-editor of *The Medical Management of AIDS*, the most widely used HIV medicine clinical textbook.

Part II. Management Plan

II.1 Overview of Management Plan

Coordinating Center. The QUERI-HIV/Hepatitis Coordinating Center is responsible for the development and implementation of the Strategic Plan. The management plan and structure are designed to provide EC members, QUERI-affiliated investigators, and project staff the support, direction, and oversight that they require. Coordinating Center leadership is comprised of the (1) Research Co-Coordinator, (2) Clinical Coordinator, and (3) Implementation Research Coordinator (IRC), assisted by the (4) Administrative Coordinator (AC). Scientific specialists and support staff (statisticians, programmers, and project managers) are based at each of the two core healthcare systems (Greater Los Angeles [GLA] and New England - Bedford), participating in project teams. Several senior scientists also play key consultative roles shaping the QUERI-HIV/Hepatitis trajectory.

Tasks, roles, and responsibilities are divided between the QUERI-HIV/Hepatitis centers at GLA and Bedford. Drs. Steven Asch (PI) and Allen Gifford are Research Coordinators and share management decisions and strategies for the QUERI program. Dr. Matthew Goetz is Clinical Coordinator, and representative to the national Treatment Assessment Group. Implementation research projects are managed from both centers, and led by center scientists and staff.

QUERI-HIV/Hepatitis Operations Core (GLA). QUERI operations and submission of the QUERI center grant are based at the VA GLA, where Dr Asch continues to have direct supervisory responsibility for the IRC and the AC. Core quantitative analytic resources (Dr Hoang) and educational outreach (Dr Knapp) and implementation expertise (Dr Henry) are concentrated here, including liaising with national clinical groups active in HIV and hepatitis care, other QUERIs, the OI&T, PHSHG and other key stakeholders, as well as providing expertise to sites interested in using HIV/Hepatitis QUERI products.

A vital national operations outreach role is managed at GLA by Jane D. Burgess, ACRN, MS, former VA Deputy Chief Consultant of the VHA Public Health Strategic Health Care Group,

currently jointly employed by PSHG and QUERI-HIV/Hepatitis. Other GLA-based investigators contribute to core projects and are listed in the staff and executive committee roster (section II.2).

QUERI-HIV/Hepatitis Methods Core (Bedford). The Methods Core is comprised of Economic Methods and Qualitative Methods components. This Core brings experts to the QUERI who will both initiate projects and serves as specialist resources to other QUERI-HIV/Hepatitis projects nationwide. Joanne Dussault, AS, the program assistant at CHQOER in Bedford, is responsible for assisting project coordinators and principal investigators in all aspects of coordinating studies at the consortium sites.

QUERI-HIV/Hepatitis core resources are bicoastal, facilitating development of projects on a truly national basis. However the geographic separation requires special procedures for personnel to stay linked regarding all program-related issues and activities. Each week, QUERI-HIV/Hepatitis has an hour group meeting of all core investigators and staff, conferenced by telephone between GLA and New England. This meeting includes brief project updates, tracking of manuscripts/presentations, operations outreach, selected project-specific problem-solving, and stakeholder relationships.

Joint Infrastructure-Building Activities. The QUERI-HIV/Hepatitis management plan includes a small number of *infrastructure activities* to support QUERI goals. First, we are working with the VA CIDER center based at VA Boston to make our web site more usable and accessible. Second, we are formalizing a communication plan in collaboration with PSHG to distribute HIV testing, and other disease management communications tools to clinics. We plan generalizable communication guidelines that can be distributed to other QUERIs seeking to maximize communication.

Executive Committee. Our mission and goals are supported by QUERI-HIV/Hepatitis Executive Committee, which serves as a board of directors, working as a group to help oversee management of the research portfolio. The QUERI-HIV/Hepatitis EC is a distinguished group of HIV/Hepatitis leaders including researchers, clinicians, operations managers, and patients. The Research Coordinators (Drs. Asch and Gifford) chair the EC.

To facilitate EC input, the Coordinating Center convenes bimonthly conference calls and one or more annual face-to-face group meetings. As we have noted in previous reports, our proliferation of activities and geographic expansion has made it increasingly difficult to have face-to-face meetings with the whole committee, so we have opted for meetings of subgroups with specific expertise that often have less structure but are most productive. In addition, EC members discuss progress and provide guidance and direction for individual projects.

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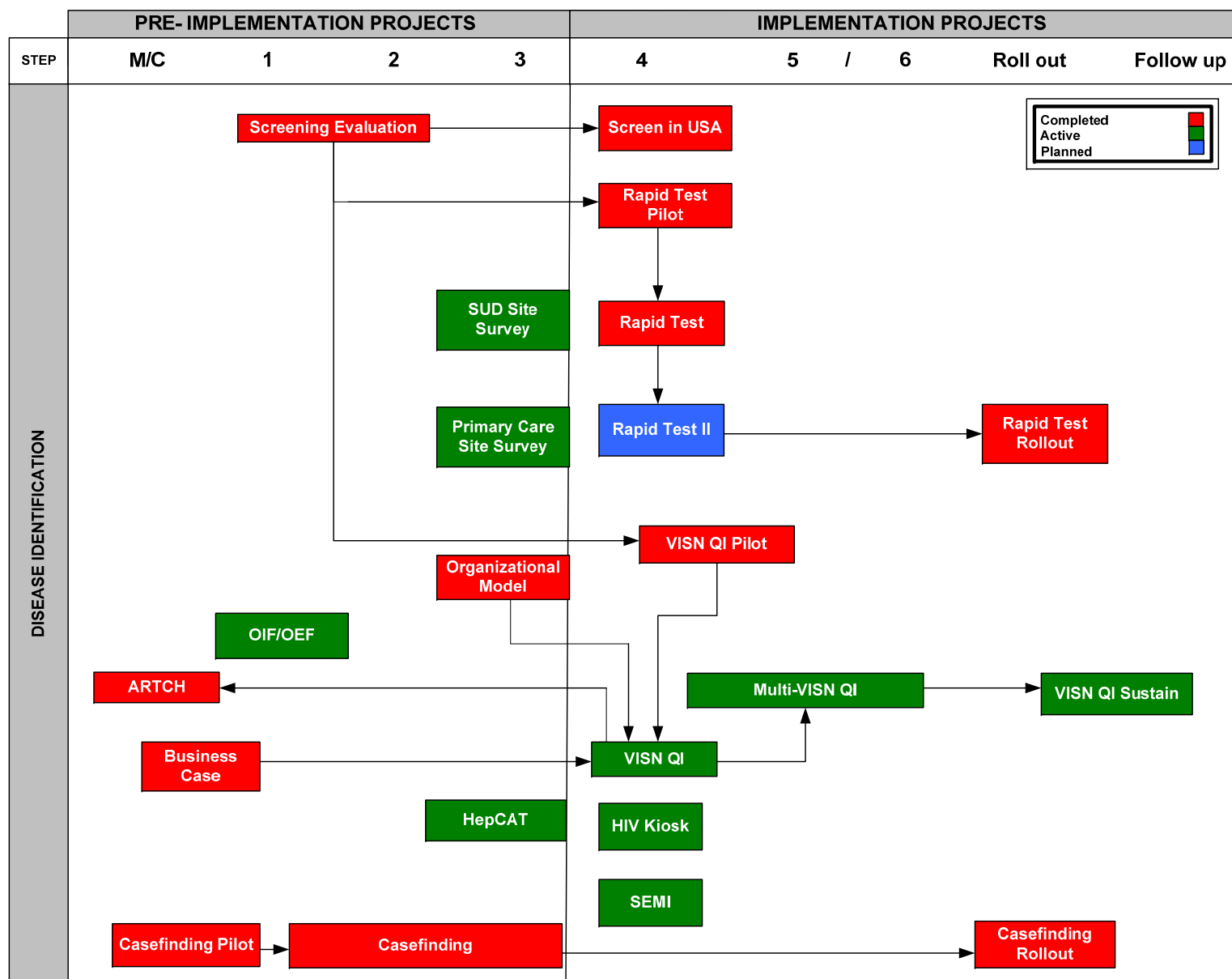
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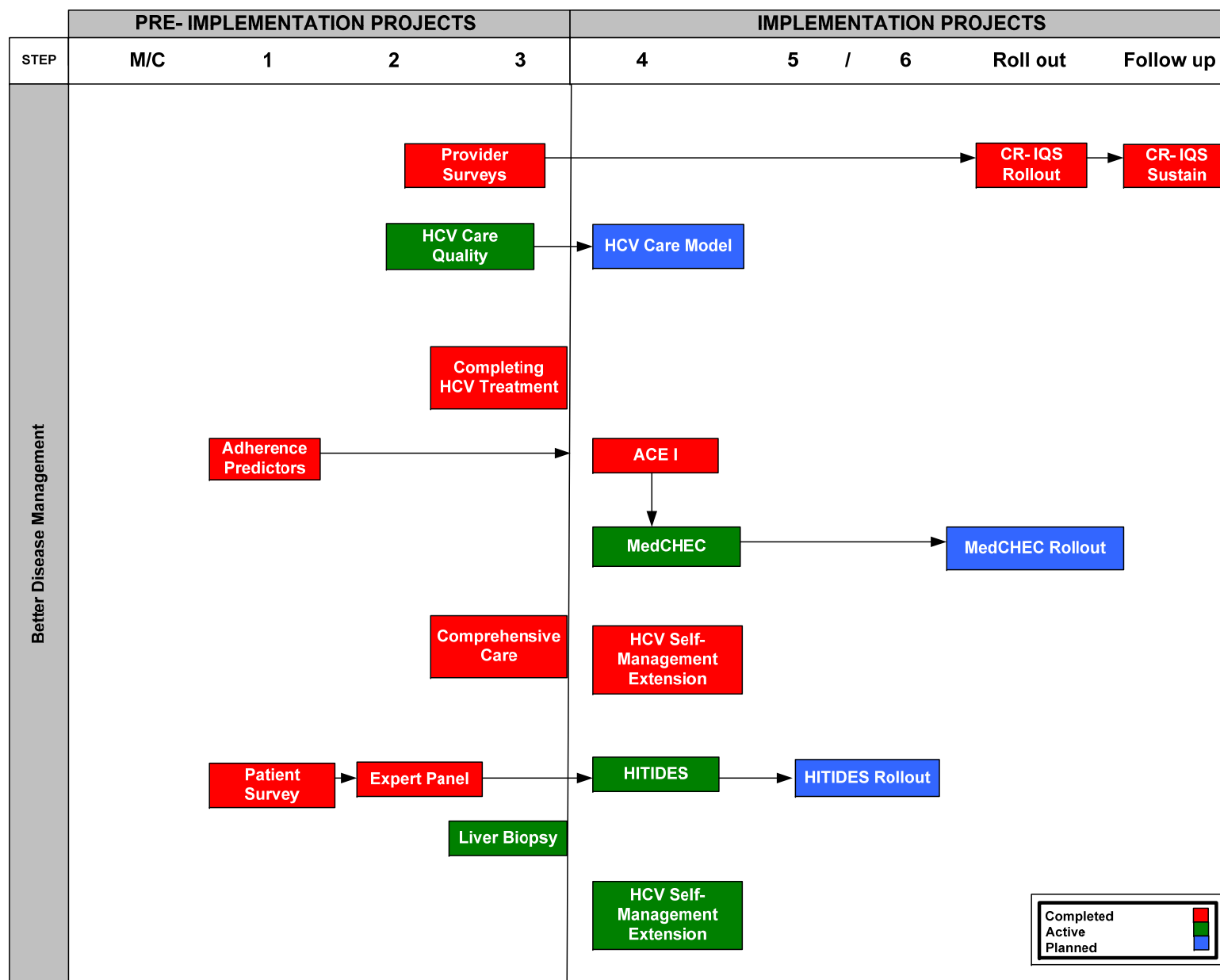
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Figure 3. QUERI Center/VHA Collaborations



Figure 4. QUERI Center Implementation Pipeline





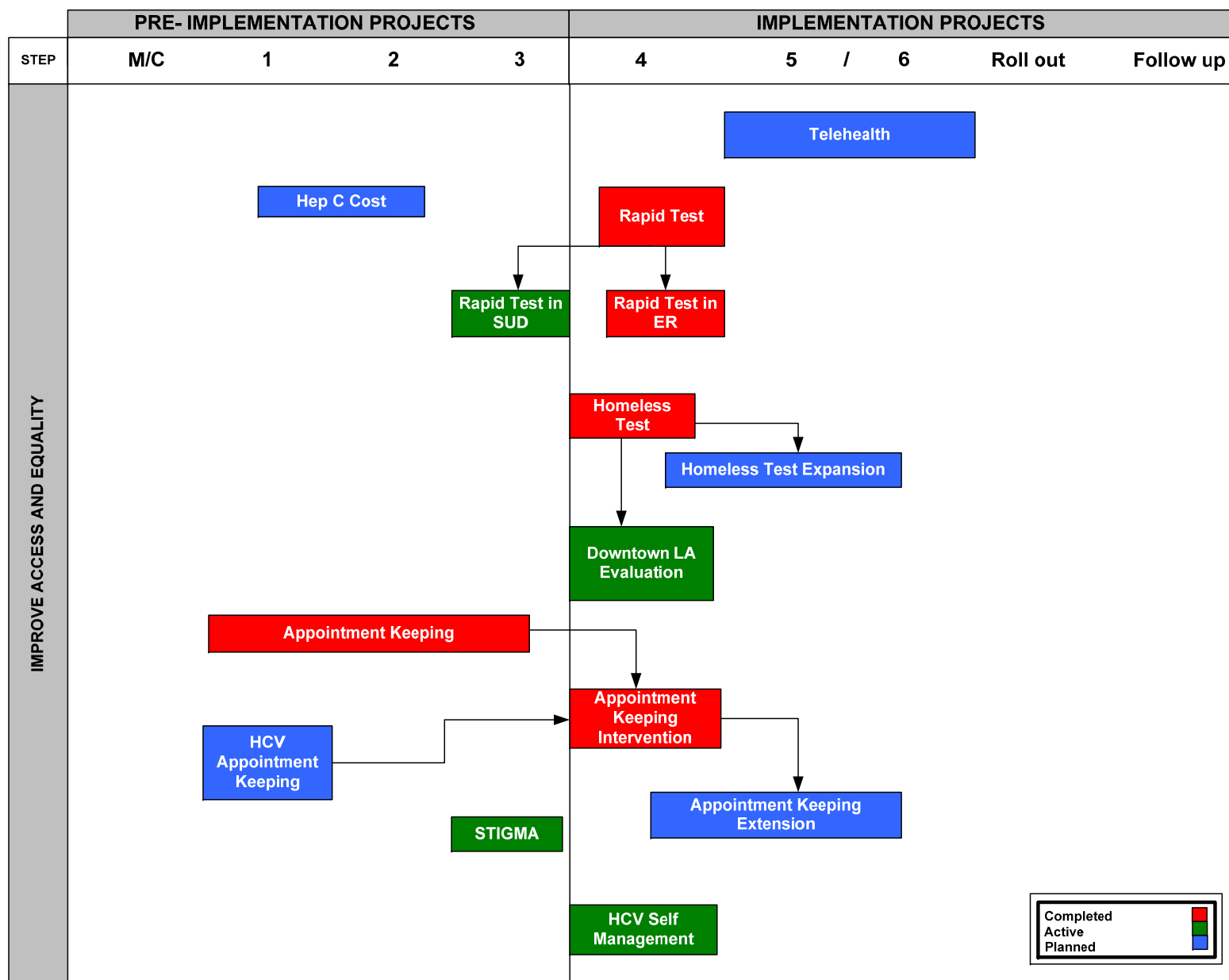


Figure 5. Implementation Science Goals

QUERI HIV-Hepatitis Implementation Science Goals	
EVIDENCE	
Goal:	Understand how evidence can be weighed and interpreted differently by operational and by research partners
Sub-Goal:	Conduct an ethnographic analysis of the research and operations partners engaged in an implementation project.
	The Organizational Model project provided an opportunity during 2008 to explore the effects of interpretations of evidence on implementation. This project used qualitative and ethnographic participant-observation methods. In the interest of improving our own procedures, we in QUERI-HIV/Hepatitis sought to evaluate ourselves and our clinical and operational partners. Individual qualitative interviews were collected, audio-recorded, and analyzed by an experienced anthropologist of health and healthcare systems, with the goals of describing the factors that influence the decisions and actions. A key finding is that researchers and managers interpret and apply evidence differently. A broad (but generally valid) conclusion of the work is that managers tend to value timeliness and direct relevance of evidence to their own circumstances, while researchers value validity and generalizability. Timeliness is in comparison quite unimportant – researchers may respond to a pressing clinical problem with an elegant and valid study that, in the view of managers, will produce an answer years after they have made a decision and forgotten the question. Analysis of these qualitative and ethnographic data from partners in implementation shows the very different interpretations different partners put on evidence.
CONTEXT	
Goal:	Understand how provider, patient, clinic, facility and VISN characteristics (e.g., structural, cultural, leadership, interpersonal) influence the readiness/capacity to adopt and/or sustain implementation of evidence-based practices.
	Our previous activities have principally centered on analyses of the structural, cultural, leadership, interpersonal characteristics that constitute the facilitators and barriers to the implementation of our HIV testing initiatives (VISN QI , Multi-VISN QI , Rapid Test in ER , ARTCH and Rapid Test). The level of the analyses (e.g., patient, provider, clinic, facility or VISN) necessarily depends on the scope of the project. Thus in the ARTCH project, we have assessed the importance of provider and patient attitudes towards HIV testing in the ARTCH project, whereas as part of the Appointment Keeping project we compared the patient demographic and clinical characteristics between the intervention and control facilities to identify characteristics associated with greater appointment adherence. Finally, in the VISN QI , Rapid Test in ER , and Rapid Test projects we have assessed the relationship between clinic-level physician and nursing staffing models and responsibilities, and the importance of support from facility level administrative personnel and opinion leaders on the successful implementation and sustenance of these projects. As a planned part of our flagship, ongoing Multi-VISN QI project we will assess extend the generalizability of these clinic and facility level evaluations and assess VISN level characteristics that shape the effectiveness of our interventions in our to improve HIV testing rates.
FACILITATION	
Goal:	Develop and evaluate the effectiveness of various facilitation strategies for implementing evidence-based practices at the clinic- and facility-level

QUERI HIV-Hepatitis Implementation Science Goals

Subgoal: Develop and evaluate the feasibility and effectiveness of team-based facilitation strategies to prepare VA for network- and national-level implementation of strategies to increase HIV testing

A principal goal of the **Multi-VISN QI** is to evaluate the effectiveness of differing strategies of implementing the intervention that was developed under the **VISN QI** project to promote HIV testing. In particular, we plan to critically evaluate the effectiveness of an implementation strategy that relies heavily on a carefully structured and controlled intervention program that is closely directed by the project team with that of an implementation strategy that instead relies on a train-the-trainer model. Detailed qualitative and quantitative evaluations will be performed to determine the relative effectiveness of these strategies. This work is being conducted with the goal of providing a firm foundation for a national roll-out of this program.